1634

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of the Application of

Stephen Michnick et al

Serial Number: 09/870,018

Filed: May 31, 2001

For: A PROTEIN FRAGMENT COMPLEMENTATION ASSAY (PCA) FOR THE DETECTION OF PROTEIN-PROTEIN, PROTEIN-SMALL MOLECULE AND PROTEIN-NUCLEIC INTERACTIONS BASED ON THE *E. COLI* TEM-1 β-LACTAMASE

Group Art Unit: 1634
Examiner: Jeffrey Norman Fredman

ELECTION WITH TRAVERSE UNDER 37 CFR 1.143

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1450

Dear Sir:

Responsive to the Office Action dated August 20, 2003, (Note that the Examiner did not set a 30 day or one month for response, however Applicant is enclosing a check in the amount of $210.00 for a two month extension of time) and in compliance with 37 CFR 1.143, Applicant provisionally elects with traverse the Group I invention (claims 1-17, and 43-62) directed to an assay method comprising:

(A) generating:

(1) at least a first fragment of a reporter molecule linked to a first interacting domain and at least a second fragment of a reporter molecule linked to a second

interacting domain, or

(2) nucleic acid molecules that code for A)1) and subsequently allowing said nucleic acid molecules to produce their coded products; then,

(B) allowing interaction of said domains; and

(C) detecting reconstituted reporter molecule activity,

where said reporter molecule can react with a penicillin- or cephalosporin-class substrate.

The Group 1 election reads on claims 1-17 and 43-62.

Applicants respectfully request and urge the Examiner to examine the present application as a whole. Because of the new GATT rules, it is respectfully requested that this application be examined in its entirety, since it is not clear what the patent office's future policy will be regarding divisional practice, although recently the Patent Office has published that it is considering guidance for the Examiners on restrictions on biotechnology inventions.

Furthermore, given the climate on restriction practice, Applicants do not understand how the patent office continues to issue restriction requirements informing applicants that **they have independent and distinct inventions .** If the U.S. Patent and Trademark Office still insists on issuing restriction requirements, then applicant is entitled to 20 years for each divisional from the date of filing each divisional, not 20 years from the date of the original application. Applicants respectfully urge the Solicitor and law making officials to either abolish restriction practice or institute an official policy of 20 years from filing for subsequently filed divisionals.

The restriction requirement is respectfully traversed. 35 USC 121 is permissive, not mandatory, and accordingly MPEP 808 requires not only clarification of the reasons why inventions as claimed are independent and distinct but also the reasons for insisting on restriction therebetween. Furthermore, the Commissioners notices appearing in 934 OG 2 and 922 OG 1016 urge examination of an entire application on the merits if this can be made without serious burden on the Examiner, even in cases which includes claims to distinct or independent inventions. Applicant believes that the entire invention as claimed can be examined without serious burden to the Examiner since the assay is a fundamental part of all other aspects of the claimed subject matter and accordingly **provides unity of invention**. MPEP 800 specifically states that if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or indenpendent inventions.

Also it is noted that the restriction requirement fails to state that the many inventions are independent and distinct, rather, only distinct.

If, the Patent and Trademark Office intends to divide the present application into a plurality of Examiner-determined inventions and restrict prosecution of the present application to one aspect of the subject matter which Applicant regards as his invention, equity requires that the factual basis for so holding be clearly delineated so that the record will reflect if such a requirement is proper under 35 USC 121.

The importance of the written record clearly setting forth the reasons upon which a restriction requirement is based, particularly with respect to claims to a compound or

composition held patentably distinct by the Patent and Trademark Office over method of use claims, is increasingly apparent from a brief filed by the Justice Department in *U.S. v. Union Carbide Corp.*, an antitrust action in the U.S. District Court for Northern California seeking to invalidate U.S. Patent 3,009,855 on the insecticide "Sevin". In that case, the Patent and Trademark Office has insisted that the original application, claiming both a product and method of use, be restricted and merely alleged that the two constituted "distinct" inventions. Applicants retained product claims in the original application and canceled method claims which were presented in a divisional application. Some 20+ years later, the Justice Department argued in its brief that the restriction requirement was clearly not authorized under 35 USC 121, since the statue imposes the dual criteria that restrictable inventions must be both independent and distinct, stating in its brief:

...it is clear that the product carbaryl and its only disclosed use, e.g., killing insects, are not "independent and distinct" inventions. Since the first application expressly discloses how to use carbaryl as an insecticide in order to meet the statutory requirements for patentability, it cannot properly be said there is "no disclosed relationship" between the product carbaryl and its disclosed use as an insecticide. Nor can it be correctly said that the product carbaryl is "unconnected in design, operation or effect" with its use to kill insects. Thus it is clear that the restriction requirement which was imposed on the first application lacked authority under 35 USC 121 because that application did not claim "two or more independent and distinct inventions".

In view of the above, reconsideration and withdrawal or at least clarification of the election of species requirement and an early action on the merits are courteously requested.

Respectfully submitted,

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Date: November 20, 2003
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